IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

SANDREA SMITH, Plaintiff, v. ANGIODYNAMICS, INC., et al., Defendants.	)	CASE NO. 2:24-cv-112-RAH [WO]

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

Pending before the Court is the Defendants' *Motion to Dismiss* (doc. 8) which seeks dismissal of all claims in the Complaint. With the motion having been fully briefed and thus ripe for decision, the motion is due to be granted in part.

II. FACTS AND PROCEDURAL HISTORY

On or about April 28, 2021, Plaintiff Sandrea Smith was implanted with Defendants' implantable vascular access device called a Smart Port. (Doc. 1 ¶ 45.) The device was designed, manufactured, sold, and/or distributed by the Defendants to Smith, through her physicians and medical providers. (*Id.* ¶ 49.)

On February 23, 2022, Smith's Smart Port device was found to have fractured, which resulted in pieces of the device migrating to Smith's heart. (*Id.* ¶¶ 51–53.) Smith underwent surgery to remove the fractured pieces. (*Id.* ¶ 53.)

Smith's experience with the Smart Port device was not unique to her because, after the Defendants brought the Smart Port device to market but before Smith's device was implanted, the Defendants received large numbers of adverse event reports from healthcare providers stating that the Smart Port, once implanted, was

fracturing and migrating throughout the body, thereby causing various injuries including death. (*Id.* ¶¶ 32–33.)

In this suit, Smith brings four causes of action against the Defendants concerning her Smart Port device: (1) a violation of the Alabama Extended Manufacturer's Liability Doctrine (AEMLD); (2) Negligence; (3) Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose; and (4) Wantonness. Defendants seek dismissal of all counts. Smith concedes dismissal of her warranty claims.

III. STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint against the legal standard set forth in Rule 8: "a short plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678. Conclusory allegations that are merely "conceivable" and fail to rise "above the speculative level" are insufficient to meet the plausibility standard. *Twombly*, 550 U.S. at 555, 570. This pleading standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678. Indeed, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a causation of action will not do.'" *Id* (citation omitted).

"To decide whether a complaint survives a motion to dismiss, [district courts] use a two-step framework." *McCullough v. Finley*, 907 F.3d 1324, 1333 (11th Cir. 2018). "A district court considering a motion to dismiss shall begin by identifying conclusory allegations that are not entitled to an assumption of the truth—legal conclusions must be supported by factual allegations." *Randall v. Scott*, 610 F.3d 701, 709–10 (11th Cir. 2010). "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679. Here, Smith "bear[s] the burden of setting forth facts that entitle [her] to relief." *Worthy v. City of Phenix City*, 930 F.3d 1206, 1222 (11th Cir. 2019).

IV. DISCUSSION

A. AEMLD Claim

In Count I, Smith brings a claim under the AEMLD for defective design[1] and failure to warn. The Defendants move to dismiss this count on two grounds. First, the Defendants argue that Alabama does not recognize defective design claims under the AEMLD when the allegedly defective product is a medical device. Second, the Defendants argue the failure-to-warn claim brought under the AEMLD must be dismissed for failure to sufficiently plead such a claim.

1. Defective Design Claim

In 1976, Alabama adopted a modified version of the American Law Institute's Section 402A of the Restatement (Second) of Torts, called the AEMLD, in place of a system of strict product liability. *See Casrell v. Altex Indus., Inc.,* 335 So. 2d 128, 130–33 (Ala. 1976); *Atkins v. Am. Motors Corp.,* 335 So. 2d 134, 142 (Ala. 1976); *see also Bodie v. Purdue Pharma. Co.*, 236 F. App'x 511, 517 n.9 (11th Cir. 2007) ("Alabama does not adhere to a system of strict product liability, but instead

[1] Smith does not appear to make a manufacturing defect claim—which is to say that there was a defect in her Smart Port device caused during the manufacturing process. Rather, her theories turn on the intended design itself which makes the product unreasonably dangerous.

follows a modified version of strict liability known as the Alabama Extended Manufacturer's Liability Doctrine[.]"); *Batchelor v. Pfizer, Inc*., No. 2:12-cv-908-WKW, 2013 WL 3873242, at *2 (M.D. Ala. July 25, 2013) ("Alabama has not adopted a no-fault concept of products liability and has instead retained a fault-based system known as the [AEMLD]."). The AEMLD has been described as "a hybrid of strict liability and traditional negligence concepts." *Pitts v. Dow Chemical Co.*, 859 F. Supp. 543, 550 (M.D. Ala. 1994) (citing *Casrell*, 335 So. 2d at 132). Common law defenses—*e.g.*, contributory negligence, assumption of the risk, and, sometimes, lack of causal relation—remain available to AEMLD defendants. *Id.*

Comment *k* to § 402A acknowledges that certain products are unavoidably unsafe and are therefore subject to a special rule that such products will not be found to be unreasonably dangerous when they are accompanied by proper directions and warnings. Prescription drugs are one such category of products. As Comment *k* acknowledges:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the

> qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. *k* (emphasis in original).

States that have adopted Comment *k* have generally interpreted the Comment as allowing only failure-to-warn claims in personal injury cases involving prescription drugs, and by extension, to prescription medical devices. *See Gunter v. Bos. Sci. Corp*., No. CV N20C-11-032 PEL, 2021 WL 1921891, at *4 (Del. Super. Ct. May 21, 2021) (applying Alabama law, dismissing defective medical mesh device claim due to Comment *k*); *McMichael v. Am. Red Cross*, 532 S.W.2d 7, 11 (Ky. 1975) (blood); *McKee v. Moore*, 648 P.2d 21, 26 (Okla. 1982) (intrauterine device).

In their motion to dismiss, the Defendants argue that Comment *k* applies to defective product claims in Alabama, *see Purvis v. PPG Indus., Inc*., 502 So. 2d 714 (Ala. 1987), including product claims involving prescription drugs, *see Stone v. Smith, Kline & French Lab'ys.*, 447 So. 2d 1301 (Ala. 1984). They further argue that Comment *k* applies to medical devices for the same reasons it applies to prescription drugs. Smith acknowledges the applicability of Comment *k* in Alabama but disputes its applicability to defective medical device claims.

The Court agrees with the Defendants that Comment *k* can and should apply to certain medical devices just as it applies to prescription drugs because, like drugs, certain medical devices are unavoidably unsafe products. As the Alabama Supreme Court noted in *Stone*, "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use" and "for this very reason cannot legally be sold except to physicians, or under

the prescription of a physician." *Stone*, 447 So. 2d at 1303 n.1 (citation omitted). In *Stone*, the Alabama Supreme Court held that prescription drugs reside in this category of products and therefore "in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Id*. at 1304. *See also Barcal v. EMD Serono, Inc.*, No. 5:14-cv-1709-MHH, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016).

It requires no leap to conclude that some, and perhaps most, medical devices carry risks that make them unavoidably unsafe and that they, therefore, must be accompanied by warnings. *See Emody v. Medtronic, Inc*., 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003) (finding at summary judgment that "an implantable, prescription-only medical device" is an unavoidably unsafe product). But the Court is unwilling to apply a blanket rule of application across all medical devices as the Defendants seem to argue. Instead, the applicability of Comment *k* to a medical device must be determined on a case-by-case basis. *See e.g, Bryant v. Hoffmann-La Roche Inc.*, 585 S.E. 2d 723, 726–27 (Ga. Ct. App. 2003); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 733 (Fla. Dist. Ct. App. 1991); *Weiss v. Fujisawa Pharm. Co.*, No. 5:05-527-JMH, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W. 2d 827, 837 (Neb. 2000); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 n. 2 (Okla. 1994). And at present, the Court cannot discern at this early stage of the proceedings whether Comment *k* should apply. Most likely Comment *k* does apply, but that is a determination for another day when additional facts are presented about the Smart Port device. As a result, the Defendants' motion seeking dismissal of Smith's AEMLD defective design claim on the basis of Comment *k* will be denied.

2. Failure-to-Warn Claim

Aside from a defective design, Smith also makes a failure-to-warn claim under the AEMLD. (Doc. 1 ¶ 86.) The Defendants argue this claim should be dismissed because Smith does not satisfactorily identify the contents of the alleged warnings or how they were inadequate.

In AEMLD cases involving unsafe prescription drugs, "the adequacy of the [manufacturer's] accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Stone*, 447 So. 2d at 1304. Alabama courts follow the learned-intermediary doctrine, in which a "manufacturer's duty to warn" a consumer about a drug "is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* (quoting *Reyes v. Wyeth Lab'ys*., 498 F.2d 1264, 1276 (5th Cir. 1974)). This also includes a duty to provide instructions to physicians about how to mitigate warned-of risks. *Blackburn v. Shire U.S., Inc*., No. 1210140, 2022 WL 4588887, at *8 (Ala. Sept. 30, 2022) ("The adoption of Comment *k* in *Stone* provided a strong indication that a prescription drug manufacturer's duty to warn is not necessarily limited to listing a drug's known side effects but may also include directions for mitigating those side effects."). "The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient." *Id.* at *5 (quoting *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 672–73 (Ala. 2014)).

However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for any injuries to the patient. *See Fields v. Eli Lilly & Co.*, 116 F. Supp. 3d 1295, 1304 (M.D. Ala. 2015). The patient must show that the manufacturer failed to warn the physician of a risk not

otherwise known to the physician and that the failure to warn "was the actual and proximate cause of the patient's injury." *Id.*

Smith's Complaint discusses warnings to "consumers," "healthcare providers," "the public," "Plaintiff," and "Plaintiff's physician." (Doc. 1 at ¶¶ 86–93.) To the extent that the Complaint's failure-to-warn claim implicates warnings to Smith herself or consumers in general, the claim is due to be dismissed under the learned intermediary doctrine. *See Batchelor*, 2013 WL 3873242, at *2 ("Defendant had no duty to warn Plaintiff, only to warn her physicians adequately and honestly[.]").

As it concerns Smith's physicians, the Defendants argue the Complaint fails to state a claim because its allegations are generalized, vague and conclusory and do not provide enough information about which warnings are alleged to be inadequate, nor does it sufficiently allege causation. *See, e.g.*, *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 608-09 (11th Cir. 2008) (finding failure to warn claim inadequate under Florida's learned intermediary doctrine where "[n]owhere does the complaint recite the contents of the warning label or the information available to [the] physician or otherwise describe the manner in which the warning was inadequate. Count I only asserts that the warning was insufficient because it failed to warn of various dangers of the use of this [prescription drug], without explaining either the information available to [the] physician at the time of the administration of the drug or how the contents of the label were inadequate.").

In response, Smith points to allegations in her Complaint that she claims state a plausible failure-to-warn claim. The Complaint alleges that the catheter component of the Smart Port device uses barium sulfate, which is known to degrade the mechanical integrity of silicone, and therefore the material from which the Smart Port device is made, and this causes microfractures and other failures in the catheter that can migrate and perforate the inside of the heart, causing injuries such as

hemorrhages, cardiac/pericardial tamponade, cardiac arryhthmia, and severe and persistent pain. The Complaint further alleges that the Defendants have been aware of these issues because the Defendants have received large numbers of adverse event reports from healthcare providers and that the Defendants "intentionally concealed the severity of complications caused by the Smart Port and the likelihood of these events occurring" (doc. 1 at ¶ 38), and "intentionally underreported the number and nature of the adverse events associated with fracture and migration of the Smart Port to Plaintiff's health care providers," (*id*. ¶ 91). The Complaint later alleges that the Defendants advertised the Smart Port device as a safe device when they knew that it was not safe and Defendants knew of the defective nature of the Smart Port device and its propensity to cause serious injuries. The Complaint further alleges that the Defendants' messaging and communications suggested that fractures of the catheter part of the device could only occur because of incorrect physician placement rather than "due to defects in the design, manufacturing and lack of adequate warnings," and that "Defendants provided incomplete, insufficient and misleading information to physicians" causing "the dissemination of inadequate and misleading information to patients, including the Plaintiff." (*Id*. ¶¶ 40–41).

And specific to Smith, the Complaint alleges that her physician implanted her Smart Port device on April 28, 2021, that on February 23, 2022 her medical providers discovered that the Smart Port catheter had fractured thereby causing immediate sharp pain, and that she underwent two surgeries on or about that date to remove catheter fragments. (*Id*. ¶¶ 50–53.) It also alleges that "[i]n reliance on Defendants' representations, Plaintiff's doctor was induced to and did use the Smart Port," and that "Plaintiff consented to undergo implantation of the Smart Port." (*Id*. ¶¶ 60–61.) Smith further alleges that "[n]either [she] nor her physicians were aware, by warning or otherwise, of the defects of Defendants' Smart Port, and would not have used and/or consented to undergo implantation of the Smart Port had they been

aware of the defective nature of the device," (*id*. ¶ 65), that "[n]o reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the Smart Port in the manner as directed, had those facts been made known to the prescribing healthcare providers or patients," (*id*. ¶ 86), and that the "Smart Port was not accompanied by proper warnings and instructions to physicians and the public regarding potential adverse side effects associated with the Smart Port and the comparative severity and duration of such adverse side effects." (*Id*. ¶ 86.) And as "a direct and proximate result of Defendants' lack of sufficient warnings and/or instructions, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss." (*Id*. at 95.)

At this stage of the proceedings, the above allegations and others contained in the Complaint are sufficient to set out a plausible failure-to-warn claim. The claim clearly indicates that the Defendants were aware of the fracturing and migration risks, that they misled the medical community and Smith's physician, and that the injuries described in the Complaint would not have occurred but for the Defendants' wrongful conduct. While the Complaint could have been better drafted, the Complaint has articulated a reasonable set of facts (and the inferences flowing from those facts) that could make the Defendants liable for failure to warn.

B. Negligence and Wantonness Claims

In Counts II and IV, Smith brings claims of negligence and wantonness associated with her Smart Port device. The two tort claims largely mimic the allegations made the basis of her AEMLD claim but with more detail surrounding the Defendants' duties to test, analyze, and surveil the Smart Port device, as well as advertising and promoting the device in the context of issuing warnings about the device given its risks. The Defendants move to dismiss both claims, arguing that the claims are duplicative and subsumed by the AEMLD claim. Smith responds that negligence and wantonness claims are not per se subsumed under the AEMLD and

that the cases relied upon by the Defendants are dated and have been undermined by more recent cases.

First, it is clear that Smith's negligence and wantonness theories are not subsumed by the AEMLD. They are distinct claims, and thus the Defendants' argument on this basis is rejected. *See Spain v. Brown & Williamson Tobacco Corp*., 872 So. 2d 101, 105–06 (Ala. 2003) (explaining that the AEMLD does not abrogate the common law, and that negligence and wantonness claims may be "viable alternatives to [an] AEMLD claim"); *Tillman v. R.J. Reynolds Tobacco Co*., 871 So. 2d 28, 35 (Ala. 2003) ("We will not presume to so define the boundaries of the judicially created AEMLD so that it subsumes the common-law tort actions of negligence and wantonness[.]"); *Weeks v. Wyeth, Inc*., No. 1:10-cv-602-MEF, 2011 WL 1216501, at *4 (M.D. Ala. Mar. 31, 2011); *Vesta Fire Ins. Corp. v. Milam & Co. Const*., 901 So. 2d 84, 102 (Ala. 2004) (rejecting premise that the AEMLD subsumes common-law tort actions of negligence and wantonness).

Nevertheless, whether Comment *k* also applies to Smith's negligent and wanton defective design claim is another matter. Although AEMLD claims and common law negligence/wantonness claims "have different elements that must be proven . . . there is nevertheless a measure of commonality between those claims." *McMahon v. Yamaha Motor Corp. U.S.A*., 95 So. 3d 769, 772 (Ala. 2012) (citations omitted). Indeed, under both theories, Smith must show that "the product at issue is defective"; that is, that it is unsafe when not accompanied by proper directions and warnings. *Id.* Comment *k*, however, limits how a plaintiff can prove a "defect." *See* Restatement (Second) of Torts § 402A cmt. *k* (stating that an unavoidably unsafe product, "accompanied by proper directions and warning, is *not defective*[.]" (emphasis added)). The Alabama Supreme Court has found the safety element common to both strict liability and negligence claims. *See McMahon,* 95 So. 3d at 772.

Indeed, in *Stone*, the Alabama Supreme Court specifically linked the unavoidably unsafe exception to negligence principles. *Stone*, 447 So. 2d at 1303 n.2 ("The requirement that the product be unreasonably dangerous, as amplified by comments j and k, produces essentially the same result as traditional negligence theory[.]") (quoting R. Merill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 31 (1973)). Because the exception's rationale turns on the notion that prescription drugs (and therefore medical devices) are desirable even though they may never be made fully safe, the Court concludes that Comment *k* equally applies to design defect claims outside the AEMLD. *See Barcal*, 2016 WL 1086028, at *3 (dismissing a negligence claim based on a drug's defective design because comment *k*'s rationale is "equally applicable" to negligence claims); *McDaniel v. Mylan, Inc*., No. 7:19-cv-209-LSC, 2019 WL 11638407, at *5 (N.D. Ala. Dec. 16, 2019). But because the Court punts the issue of Comment *k* under the AEMLD to a later stage as it concerns the Smart Port device, the issue will also be punted as to Smith's defective design claims brought under theories of negligence and wantonness. And since Comment *k* does not preclude a failure-to-warn claim, the negligent and wanton failure-to-warn claim can proceed. Accordingly, the Defendants' motion to dismiss these claims will be denied on all theories.

V. CONCLUSION

Accordingly, it is **ORDERED** that Defendants' *Motion to Dismiss* (Doc. 8) is **GRANTED in part** and **DENIED in part as follows:**

1. The motion is **GRANTED** as to Count III (breach of warranties); and
2. The motion is **DENIED** as to Count I (AEMLD), Count II (Negligence) and Count IV (Wantonness).

DONE on this the 23rd day of April 2024.

R. AUSTIN HUFFAKER, JR.
UNITED STATES DISTRICT JUDGE